IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

CASES IDENTIFIED IN EXHIBIT A

Master File No. 2:12-MD-02327 MDL No. 2327

JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

REPLY IN SUPPORT OF PLAINTIFFS' MOTION TO LIMIT THE OPINIONS AND TESTIMONY OF DR. PETER L. ROSENBLATT

The Plaintiffs in the causes pending in this MDL and identified in the attached "Exhibit A" ("Plaintiffs") hereby submit this *Reply in Support of Plaintiffs' Motion to Limit the Opinions and Testimony of Dr. Peter L. Rosenblatt*. Pursuant to Federal Rules of Evidence 702 and 403 and in further support of granting *Plaintiffs' Motion to Limit the Opinions and Testimony of Dr. Peter L. Rosenblatt*, Plaintiffs would show this Honorable Court as follows:

I. SUMMARY OF ARGUMENT

1. Dr. Peter L. Rosenblatt's ("Dr. Rosenblatt") general causation opinions should be limited and/or excluded as described and demonstrated in Plaintiffs' Motion to Limit and memorandum in support thereof, which were filed on July 17, 2016 (hereinafter collectively referred to as "Motion to Limit"). Defendants have filed a memorandum in opposition to Plaintiffs' Motion to Limit ("Defendants' Response" or "Response"), however, Defendants fail to present evidence therein demonstrating that Dr. Rosenblatt's challenged opinions are

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¹ See Dkt. #2425 and Dkt. #2428.

sufficiently reliable so as not to be limited by the Court.² For these reasons and more, Plaintiffs' Motion to Limit should be granted.

II. ARGUMENT & AUTHORITIES

A. ROSENBLATT'S OPINIONS REGARDING THE SAFETY AND EFFICACY OF MESH:

- 2. First, Defendants argue that Dr. Rosenblatt's opinions regarding the safety and efficacy of mesh are not unreliable merely because he cannot testify as to what specific percentage of Prolift patients would have to experience mesh exposure for him to find Prolift defective. However, Dr. Rosenblatt could not provide *any* percentage nor even a mere range of percentages.³ Defendants admit that "[t]he specific percentage of patients who experience exposure is simply not part of Dr. Rosenblatt's methodology," yet, at the same time, Defendants assert that this fact does not prohibit Rosenblatt from providing an opinion as to the "small percentage" of patients who experience mesh exposure. The fact that Dr. Rosenblatt cannot give any percentage, or range of percentages, demonstrates that his opinion that Prolift is not defective due to the small percentage of patients who experience exposure as a result thereof clearly constitutes *ipse dixit*.
- 3. In their Response, Defendants attempt to rebut this argument by relying on the Court's opinion in *Winebarger v. Boston Scientific*. However, *Winebarger* is clearly distinguishable. Specifically, in *Winebarger*, the plaintiffs tried to exclude an expert's opinion as to the safety and efficacy of mesh because he "could not testify as to the exact statistics about his patients (i.e., how many patients he has implanted with an Uphold)." The Court allowed this expert to

² See Dkt. #2535.

³ See Dkt. #2425-4 at 60:4-61:10.

⁴ Winebarger v. Bos. Sci. Corp., No. 2:13-cv-28892, 2015 U.S. Dist. LEXIS 53892, at *99 (S.D. W. Va. Apr. 24, 2015).

testify because "such detail is not required under *Daubert* to opine as to the 'large-scale and efficacy of the Uphold device." 5

- 4. Dissimilarly, here, Dr. Rosenblatt specifically opines that the Prolift device is not defective and bases this opinion on the "small percentage" of patients who, according to him, experience mesh exposures. Moreover, here, Plaintiffs do not challenge Rosenblatt's opinion based on his failure to provide "exact statistics," but rather, argue that the fact that Rosenblatt cannot provide even a range of percentages or approximate percentage demonstrates that his opinion is unreliable. *Winebarger* is clearly distinguishable, and this argument in Defendants' Response is without merit.
- 5. Second, Defendants argue that Plaintiffs fail to cite any evidence demonstrating why such data or approximate data should be a part of Dr. Rosenblatt's methodology in order to render Rosenblatt's opinion as to the safety and efficacy of mesh reliable. However, Defendants overlook that they—not Plaintiffs—have the burden to present evidence showing that Dr. Rosenblatt's opinions and methodology *are* reliable. Defendants wholly fail to do so in their Response, and Plaintiffs' Motion to Limit should be granted accordingly.
- 6. Third, Defendants argue that Plaintiffs "assume" that Dr. Rosenblatt ignores studies that show high rates of exposure without explaining why he fails to take such studies into account. Defendants further assert that Plaintiffs did not ask Dr. Rosenblatt about any of the specific studies in his deposition. As previously stated, it is Defendants' burden to present evidence showing that Dr. Rosenblatt's opinions are reliable. Here, regardless of any purported failure of Plaintiffs to inquire into Rosenblatt's bases for his opinions during his deposition, Defendants still have failed to present any evidence explaining why Dr. Rosenblatt failed to

⁵ *Id.* at *100.

⁶ Md. Cas. Co. v. Therm-O-Disc, 137 F.3d 780, 783 (4th Cir. 1998).

 $^{^7}$ Id

consider the mesh studies showing high rates of mesh exposure and why his opinion is still reliable despite this failure.

7. Importantly, this Court recently excluded a plaintiff's expert opinion for substantially similar, if not identical, reason. In *Ramsey v. Bos. Sci. Corp.*, the plaintiff's expert opined that there is a greater than fifty percent (50%) complication rate of pain in women with polypropylene mesh. The expert acknowledged in his deposition that contrary studies exist, but the Court excluded this opinion as unreliable because the expert did not provide an explanation for why he disagreed with the contrary studies. Likewise, here, Defendants do not point to any testimony of Dr. Rosenblatt or present any evidence explaining why Rosenblatt did not consider mesh studies showing high exposure rates in forming his opinions and why his opinions should be deemed reliable despite this failure. If the Court is not inclined to exclude all of Rosenblatt's opinions as to the safety and efficacy of the mesh devices involved in Plaintiffs' cases, at the very least, Plaintiffs assert that Rosenblatt's opinion that "[t]he Gynemesh PS mesh used in Prolift is not defective just because a small percentage of patients might experience mesh exposures or other well-known and acceptable complications" should be excluded as unreliable.

B. ROSENBLATT'S OPINION THAT "SEVERAL MILLION WOMEN" HAVE BENEFITTED FROM MESH:

8. In their Response, Defendants argue that Plaintiffs' Motion to Limit should not be granted as to Dr. Rosenblatt's opinion that millions of women have benefitted from mesh because, according to Defendants, "Plaintiffs' counsel phrased the question [to Rosenblatt] referring to 'polypropylene,' not any one specific product." First, this argument is disingenuous

⁸ No. 2:13-cv-15223, 2016 U.S. Dist. LEXIS 65820, at *12 (S.D. W. Va. May 19, 2016).

⁹ *Id.* at *12-13.

¹⁰ See Dkt. #2425-3 at p. 45.

because Dr. Rosenblatt was clearly testifying regarding polypropylene vaginal mesh slings during this portion of the deposition. He specifically stated that "you've got several million women that have benefited greatly from this technology over a period of, you know, over 17 years, probably more like 20 years at this point including Europe." which is clearly a reference to TVT as Dr. Rosenblatt's report states that TVT was introduced in 1998. 12 Defendants also ignore the three (3) other occasions during his deposition when Dr. Rosenblatt specifically testifies that vaginal mesh benefitted millions of women—testimony that Plaintiffs specifically quoted and enumerated in their Motion to Exclude. 13 Defendants' argument that Dr. Rosenblatt was testifying about polypropylene mesh in general is without merit and should be disregarded by this Court.

9. Lastly, Defendants argue that Dr. Rosenblatt's opinion is supported by a single AUGS-SUFU position statement. However, this position statement does not constitute the type of scientific, peer-reviewed study that is typically cited by medical experts to support their conclusion and opinions. As Defendants are fully aware, this position statement is clearly conclusory and insufficient to support Dr. Rosenblatt's medical and scientific opinions and conclusions. Defendants have not shown how the AUGS-SUFU statement is a reliable basis for Dr. Rosenblatt to be able to reliably opine that "several million women...have benefited greatly from" transvaginal mesh.

C. ROSENBLATT'S OPINIONS ON "FEAR MONGERING" SURROUNDING MESH AND WOMEN BEING TAKEN ADVANTAGE OF BY MEDICAL LENDERS:

10. Defendants argue that Dr. Rosenblatt's opinions on "fear mongering" surrounding mesh and women being take advantage of are reliable because "[h]e bases this testimony on his

¹¹ *See* Dkt. #2425-4 at 87:13-88:6 (emphasis added). ¹² *See* Dkt. #2425-3 at p. 12.

¹³ See Dkt. #2425-4 at 65:16-25; 80:2-21; 122:24-123:7; see also Dkt. #2428 at p. 7-8.

personal experience of speaking with patients who tell him that, due to this advertising, they are afraid to have mesh implants and prefer alternatives such as Burch procedures." ¹⁴ This basis for Dr. Rosenblatt's opinion clearly constitutes inadmissible hearsay pursuant to Federal Rule of Evidence 801. Further, the articles that Defendants state supports Dr. Rosenblatt's opinions, in fact, do not support the conclusion that women are afraid of mesh because of "fear mongering" and merely compare transvaginal mesh surgery to traditional surgery. Moreover, the article Defendants cite and attach clearly states that "[t]he purpose of this response is to demonstrate that TVM is an important tool in our surgical armamentarium that may be the best option in some cases."15

- Next, Defendants also cite a single Reuters article in support of Dr. Rosenblatt's 11. opinion that women are being taken advantage of by medical lenders, but this article dealing with a specific incident is not sufficient for Dr. Rosenblatt to be able to opine as generally and as broadly as he does. These studies and articles offer absolutely no support for Rosenblatt's opinions and only further show that Dr. Rosenblatt does not have any reliable bases for these opinions.
- Finally, in their Response, Defendants wholly fail to address, or even attempt to rebut, 12. Plaintiffs' arguments that the probative value of Rosenblatt's opinions, if any, substantially outweigh the real dangers of unfair prejudice to Plaintiffs, confusion of issues, and misleading of the juries. As such, the Court should find that Defendants have conceded this argument/issue by failing to respond to it at all in their opposition memorandum.

See Dkt. #2535 at p. 9.
See Dkt. #2535-6 at p. 5.

III. CONCLUSION

13. Plaintiffs' Motion to Limit should be granted, and the opinions of Dr. Rosenblatt

outlined therein should be limited and/or excluded as they fail to meet the reliability and

admissibility standards set forth in Rule 702 and Daubert. Furthermore, pursuant to Rule 403,

the opinions of Dr. Rosenblatt described in Plaintiffs' Motion to Limit should be excluded and/or

limited because the probative value of such opinions, if any, substantially outweigh the dangers

of unfair prejudice to Plaintiffs, confusion of issues, and misleading of the jury/juries.

Respectfully submitted,

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ATTORNEY FOR PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing has been forwarded to all counsel of record on this 18th day of August, 2016, in accordance with the Federal Rules of Civil Procedure.

/s/ Mark Sparks

Mark Sparks